DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 12, 2014

CAO Group Incorporated
Mr. Robert K. Larsen
Regulatory Affairs Manager
4628 West Skyhawk Drive
West Jordan, Utah 84084

Re: K142223
Trade/Device Name: Pilot Pro Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 4, 2014
Received: August 13, 2014

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142223

Device Name
Pilot Pro Diode Laser

Indications for Use *(Describe)*
The Pilot Pro Diode Laser is indicated for the procedures of

removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation

on soft tissue in the fields of

otolaryngology (ear, nose, and throat), dentistry and oral surgery, arthroscopy, gastroenterology, dermatology, podiatry, plastic surgery, urology, and gynecology.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

CAO Group, Inc.
4628 West Skyhawk Drive
West Jordan, UT 84084
Tel: 801-256-9282 Fax: 801-256-9287

Prepared By: Robert K. Larsen,
Preparation Date: August 5, 2014

Device Name:

Trade Name:	Pilot Pro Diode Laser
Common Name:	Soft Tissue Diode Laser
Product Classification:	Powered Laser Surgical Instrument

Legally Marketed Predicate Devices for Substantial Equivalence:

DenLaser 800 Plus, manufactured by CAO Group, Inc. (K062619)

Rationale for Substantial Equivalence:

The aforementioned device has identical indications for use with that of the present device for removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue in the fields of otolaryngology (ear, nose, and throat), dentistry and oral surgery, arthroscopy, gastroenterology, dermatology, podiatry, plastic surgery, urology, and gynecology.

The predicate device and submitted device have identical performance features including wavelength, power output, energy type, operating controls, and laser delivery method. The devices have identical methods of disinfection and sterilization. The devices have identical methods of control systems, safety features, and performance monitoring.

Description of Submitted Device:

The Pilot Pro Diode Laser is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 5 watts of energy output. The laser energy is delivered to the surgical site by means of an optical fiber system, which allows for the safe transmission of laser energy to the site without

creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous emission or pulse emission options.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is removable from the optical fiber system for cleaning and sterilization in between uses. The activation of the working beam diodes is completed by use of a foot-actuated switch.

Intended Uses of the Submitted Device:

The Pilot Pro Diode Laser is indicated for the procedures of

removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation

on soft tissue in the fields of

otolaryngology (ear, nose, and throat), dentistry and oral surgery, arthroscopy, gastroenterology, dermatology, podiatry, plastic surgery, urology, and gynecology.

Technological Characteristics and Substantial Equivalence:

The DenLaser 800 Plus is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 5 watts of energy output. The laser energy is delivered to surgical site by means of an optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous emission or pulse emission options.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is removable from the optical fiber system for cleaning and sterilization in between uses. The activation of the working beam diodes is completed by use of a foot-actuated switch.

Conformity to Standards:

The Precise SHP Diode Laser is designed to comply with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated June 24, 2007. The device also complies with the recognized standards of IEC 60601-2-22

Edition 2 and IEC 60825-1 Edition 1.2. The device is designed in compliance to the entirety of IEC 60601-1: 2nd Edition, IEC 60601-1-2, and IEC 60601-1-4.

Performance Data

Bench testing on an evaluation sample of the current device revealed that the device met the design criteria for essential performance, and satisfied the performance requirements indicated in 21 CFR 1010 and 21 CFR 1040. Device outputs were within performance requirements and all safety features and functions were operating correctly.

Conclusion

The Pilot Pro Diode Laser is substantially equivalent to the listed predicate device without raising any new issues of safety or effectiveness. This device shares similar intended uses, operating principles, design features, and functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.